Natural Options Corp 12/21/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-11
December 21, 2010

Claudia Muharram, President/Director
Natural Option USA Corporation
4957 SW 74th Court
Miami, FL 33155

Dear Ms. Muharram:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.natural-option.com/ in December 2010 and has determined that the product OsteOrganicCAL (a sea algae calcium compound packaged with Vitamin D3) is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Claims in the form of personal testimonials on the OsteOrganiCAL webpage:

- "My clinical results in reversing osteopenia and osteoporosis have been better than those obtained using Fosamax."
- "[M]y bone density test showed considerable improvement. My first bone density test indicated I was at risk for traumatic fracture. After I began the OsteOrganiCAL program, my follow-up test showed considerable improvement."
- "April of 1995, I had a bone scan. The result: I was diagnosed with severe osteoporosis. In May I found out about a product called OsteOrganiCAL, I took OsteOrganiCAL for three months, went and had another bone scan. My overall bone density was increased 3.9%. I have never felt better."
- "[I] had a hard fall, my hip was black and purple. My chiropractor said she had never seen any bruise that bad, without a broken hip. I am sure it was the Natural Option product [OsteOrganiCAL] that saved me from a break. Thank you so much for stronger bones."
- "[S]even months my wife has been on OsteOrganiCAL. During this time she has not fractured any bones."

Claims made under the heading "OsteOrganiCAL® CASE STUDY ANALYSIS":

- "The fall of 2003 the Osteoporosis Education Project completed a yearlong pilot study with the sea algae calcium and vitamin D product known as "OsteOrganiCAL®". The study included eleven postmenopausal women, six of whom experienced impressive gains in bone mineral density from use of the product."
- "[A]nalysis of these cases documents the potential of this novel Calcium and Vitamin D product [OsteOrganiCAL] to halt and reverse the osteoporosis process in postmenopausal women."
- "Using OsteOrganiCAL however, the few women in the sample with only moderate bone loss (osteopenia) also benefited significantly from this therapy."

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Furthermore, your product OsteOrganiCAL is misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] because the labeling for this drug fails to bear adequate directions for use.

This letter is not intended to be an all-inclusive review of your website and the products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not recur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which the corrections will be completed.

Your response should be directed to Winston Alejo, U.S. Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have any questions about this letter, please contact Mr. Alejo at (407) 475-4731.

Sincerely,
/S/
Emma R. Singleton
Director, Florida District